

2800-106
GFR:lam

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

15 APR 2002

Legal Coun.

International Division

In re Application of)
)
GJELSNES, Oddbjorn)
)
Serial No. Not Yet Assigned) PCT International No.:
) PCT/NO00/00286
Filed: Herewith) International Filing Date:
) September 1, 2000
For: METHOD AND DEVICE FOR)
COUNTING CELLS IN URINE)

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT
ABANDONED UNINTENTIONALLY UNDER 37 CFR 1.137(b)

Attention: Office of Petitions
Assistant Commissioner for Patents
Box DAC
Washington, D.C. 20231

Dear Sir:

The above-identified application became abandoned for failure to timely file the Request for Entry in the U.S. National Phase of International Application No. PCT/NO00/00286. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

02/27/2002 HNGUYEN 00000153 10069044

02 FC:241

640.00 DP

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

1. Petition fee

☒ small entity - fee \$640.00. Applicant claims small entity status.

☐ other than small entity - fee \$1,280.00.

2. Reply and/or fee

A. The fee for entering into the U.S. National Phase for PCT/NO00/00286 is

☐ has been previously filed on

☒ is enclosed herewith.

B. The issue fee of \$

☐ has been paid previously on

☐ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee of \$55.00 for a small entity of \$110.00 for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 CFR 1.137(b) was unintentional. (NOTE. The United States Patent and Trademark Office may require

additional information if there is a question as to whether either the abandonment or the delay in filing a petition under 37 CFR 1.137(b) was unintentional

WARNING: Information on this form may become public.
Credit card information should not be included on this form.
Provide credit card information and authorization on PTO-2038.

Respectfully submitted,

By G.F. Rothwell
G. Franklin Rothwell
Attorney for Applicants
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JC20 Rec'd PCT/PTO 21 FEB 2002

FORM PTO-1390		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 2800-106
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. Application No. (if known, see 37 CFR 1.5) 10/069044 Not Yet Assigned
INTERNATIONAL APPLICATION NO. PCT/NO00/00286	INTERNATIONAL FILING DATE September 1, 2000	PRIORITY DATE CLAIMED September 1, 1999	
TITLE OF INVENTION METHOD AND DEVICE FOR COUNTING CELLS IN URINE			
APPLICANT(S) FOR DO/EO/US GJELSNES, Oddbjorn et al.			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US) 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).			
ITEMS 11. TO 20. below concern other document(s) or information included:			
11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: <i>Petition to Revoke with fee check</i>			

U.S. APPLICATION NO. (If known, see 37 CFR 1.50) Not Yet Assigned 107069044		INTERNATIONAL APPLICATION NO PCT/NO00/00286		ATTORNEY DOCKET NO 2800-106	
21. <input checked="" type="checkbox"/> The following fees are submitted. Basic National Fee (37 CFR 1.492)(a)(1)-(5): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report Not Prepared by EPO or JPO. \$ 1,040 00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report has been prepared by the EPO or JPO \$ 890 00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$ 740.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but claims did not satisfy provisions of PCT Article 33(1)-(4) \$ 710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$ 100 00 <div style="text-align: right;">ENTER APPROPRIATE BASIC FEE AMOUNT =</div>				<u>CALCULATIONS</u>	<u>PTO USE ONLY</u>
				\$ 1,040.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than [] 20 [] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
Claims	Number Filed	Number Extra	Rate		
Total Claims	7 -20 =	0	X \$18.00	\$0	
Independent Claims	2 - 3 =	0	X \$84.00	\$0	
Multiple dependent claim(s) (if applicable)			+ \$280.00	\$0	
TOTAL OF ABOVE CALCULATIONS =				\$ 1,040.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ 520.00	
SUBTOTAL =				\$ 520.00	
Processing fee of \$130.00 for furnishing the English translation later than [] 20 [] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	
TOTAL NATIONAL FEE =				\$ 520.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$	
TOTAL FEES ENCLOSED =				\$ 520.00	
				Amount to be refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>520.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 02-2135 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2135. A duplicate copy of this sheet is enclosed. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: Customer No. 6449 G. Franklin Rothwell, Esq. Rothwell, Figg, Ernst & Manbeck 555 13th St., N W Washington, D.C 20004 Phone: 202/783-6040			<div style="margin-bottom: 10px;"> </div> Signature G. Franklin Rothwell Name <u>18,125</u> Registration Number		

APPLICATION DATA SHEET

Inventor Information

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Correspondence Information

Correspondence Customer Number:: 6449

Application Information

Title Line One:: METHOD AND DEVICE FOR COUNTING CELLS IN
 Title Line Two:: URINE
 Total Drawing Sheets:: ONE (1)
 Formal Drawings?: YES
 Application Type:: UTILITY
 Docket Number:: 2800-106
 Secrecy Order in Parent Appl?: NO

$\frac{1}{n} \sum_{i=1}^n \left(\frac{\partial}{\partial \theta} \log f(\mathbf{x}_i; \theta) \right)^T = 0$

Prior Foreign Applications

Foreign Application One::	19994228
Filing Date::	September 1, 1999
Country::	Norway
Priority Claimed::	Yes

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE	<i>Application Number</i>	PCT/NO00/00286
	<i>Filing Date</i>	September 1, 2000
	<i>First Named Inventor</i>	GJELSNES, Oddbjorn
	<i>Group Art Unit</i>	Unassigned
	<i>Examiner Name</i>	Unassigned
	<i>Attorney Docket Number</i>	2800-106
<i>Title of the Invention:</i> METHOD AND DEVICE FOR COUNTING CELLS IN URINE		

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Preliminary to examination on the merits, please amend the above-referenced application as follows:

Amend claims 4, 5 and 6 as shown on the following pages.

Marked-up copies of the original text of the amended claims are attached to this amendment. Material inserted is indicated by underlining and material deleted is indicated by brackets.

Clean Copy of Amended Claims

4. (Amended) A method according to claim 1, characterized in that the dye used is a flurochrome that specifically attaches to the nucleic acids of the cells, and that it is monomer cyanine flurochrome, preferably TOPRO-3.

5. (Amended) A method according to claim 1, characterized in that the mixture is analyzed in a device that measures light scatter and fluorescence from the individual cells, such as a flow cytometer.

6. (Amended) A method according to claim 1, characterized in that the analyses are preformed at a wave length >500, preferably at 635 nm.

REMARKS

The amendments to the claims are made to correct improper claim dependencies and to put the claims in the format preferred by the U.S. Patent Office. No new matter is introduced by means of these amendments.

RESPECTFULLY SUBMITTED,					
NAME AND REG NUMBER	G. Franklin Rothwell, Reg. No. 18,125				
SIGNATURE	<i>G. F. Rothwell</i>			DATE	2.21.02
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City	Washington	State	D.C.	Zip Code	20004
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031

Attachments: Marked-Up Copies of Amendments to the Claims

Amended Claims: Version with markings to show changes made

4. (Amended) A method according to claim[s] 1 [-2], characterized in that the dye used is a fluorochrome that specifically attaches to the nucleic acids of the cells, and that it is monomer cyanine fluorochrome, preferably TOPRO-3.

5. (Amended) A method according to claim[s] 1 [-4], characterized in that the mixture is analyzed in a device that measures light scatter and fluorescence from the individual cells, such as a flow cytometer.

6. (Amended) A method according to claim[s] 1 [-5], characterized in that the analyses are preformed at a wave length >500 , preferably at 635 nm.

Method and device for counting cells in urine

The present invention regards a method and a device for counting bacteria and other micro-organisms in urine from a patient. The method and the device are very quick and accurate in terms of diagnosing cystitis. The technical area of the invention is medical diagnostics. The techniques used are covered by the areas of biochemistry/microbiology, optics, fluid mechanics, electronics and computer science. The novel aspects of the invention fall mainly within the subjects of biochemistry and microbiology.

The invention involves detecting bacteria by means of light scatter and fluorescence with an improved signal-to-noise ratio when compared with prior art.

Persons suffering from cystitis have cells in their urine that should not normally be there. These cells in the urine may be bacteria and fungus, as well as the patient's own cells (somatic cells), such as leukocytes or epithelial cells.

The invention seeks, through the method and device thereof, to solve the following problem: In the case of cystitis, it takes a long time (one or more days) to count the number of bacteria in urine. This because the bacteria must be cultivated on agar discs until they form macroscopic colonies than can be seen with the naked eye. The long wait required before a diagnosis can be made is unfortunate, as the patient is often given antibiotics before a certain diagnosis has been made.

Attempts have been made to solve this problem by counting the bacteria and other cells (lymphocytes and epithelial cells) directly in the urine by using specially designed cell counting devices (flow cytometers). In order to be able to do this, the cells must be made fluorescent by adding special fluorochromes that attach to the cells. In the flow cytometer, the cells are illuminated by a beam of light as they pass the measurement point in a liquid stream (thus flow cytometry). The instrument registers the light scatter and fluorescence from each individual cell. The intensity of the scattered light is a function of among other things the size of the cell, and the intensity of the fluorescent light is a function of among other things the amount of substance made fluorescent (e.g.

nucleic acids). The concentration of cells (number of cells per ml urine) is simply determined by counting the number of fluorescent particles in the sample. This may be grouped into different types of cells based on the size of the cells (light scatter) and the content of nucleic acids (fluorescence). There are also other quick methods of measuring bacteria in urine, however these are indirect and measure the presence of cellular metabolites (dipsticks).

The main problem associated with prior art that makes use of plate counting is the time it takes. The problem with today's flow cytometers is that they are not good enough at routinely measuring bacteria in urine, which are small in comparison with somatic cells (lymphocytes, epithelial cells).

US 5 693 484 regards a method of counting and classifying cells in urine. A fluorescent dye is added to the urine sample, which dye attaches to the nucleic acids of the cells.

The cells are then illuminated with light at the blue and violet wavelengths, and analysed in a flow cytometer.

The method according to US 5 639 484 functions satisfactorily with somatic cells, but does not work well with bacteria. This is, among other things, due to the following facts:

- Using violet/blue excitation light results in auto-fluorescence, which causes the signal-to-noise ratio to be reduced at low fluorescence intensities (as in the case of bacteria).
- It is more difficult for live bacteria to absorb dye than it is for somatic cells, for several reasons.
- Firstly, the cell walls of the bacteria act as a barrier against the surroundings.
- Secondly, the bacteria may have intracellular pumps that bring the dye out again.
- Thirdly, the bacteria are considerably smaller than somatic cells, thus containing less of the cellular components that are to be stained.
- As a result of this, the fluorescence intensity per cell is low.

The present invention provides a method and a device that are reliable and quicker than the known techniques. The method consists of the following steps:

- 5 1. The urine sample from the patient is undiluted and is mixed with a fixative liquid so as to kill all the cells. The fixative liquids that may be used must be such that they render the cellular membrane permeable for absorption of the dyes (fluorochromes) mentioned below. Fixatives that may be used include ethanol, isopropanol and acetone, acetone being particularly preferred.
- 10 2. The mixture from point 1 has a buffer solution added to it, which is formulated so as to promote attachment of fluorochrome to the nucleic acids of the cells (DNA/RNA) (see point 3). At the same time, the buffer solution must prevent attachment to other cellular components. The buffer that has been found to be
15 the most optimal is the so-called TBE-buffer (90 mM Tris, 90 mM Borate, 2,5 mM EDTA, pH 8).
- 20 3. A fluorochrome is added to the mixture from point 2, which fluorochrome specifically attaches to the nucleic acids of the cells. The present method may for instance involve the use of a monomer cyanine fluorochrome.
- 25 4. The mixture from point 3 is analysed in a device that measures light scatter and fluorescence from individual cells (e.g. a flow cytometer). The excitation light has a wavelength (635 nm) such that auto-fluorescence from the cells is insignificant.
- 30 5. The results are presented on a display that shows the fluorescent particles (cells) appearing separately (different colour) from particles without fluorescence, while displaying the absolute count. Cells in the lower size range (0.5 - 2 μ m) are assumed to be bacteria.
6. Steps 1 – 5 can be performed by a novel device according to the invention, such as appears in the accompanying schematic figure.

More specifically, the invention regards a method for counting cells in a urine sample, characterised in that a fixative is added to and mixed with the urine sample; a buffer solution is added to the mixture; followed by a dye; the mixture is then analysed in a device that measures light scatter and fluorescence from individual cells; and the results are shown directly on a display.

The invention further regards a device for measuring cells in a liquid stream by means of flow cytometry, in particular bacteria in a urine sample, characterised in that it comprises pickup tubes for the urine sample, which tubes lead to one or more mixing chambers to which are also connected separate receptacles for the fixative and the staining solution that are added to the mixing chamber via adjustable multi-channel pumps; the mixing chamber is further connected to an optical flow cytometric cell that receives carrier liquid from a receptacle.

According to the method of the invention, fluorescence is achieved by staining the bacteria. The cellular membrane is broken down when the cell is fixed by a fixative liquid such as ethanol, isopropanol or preferably acetone. The fixation also inactivates any efflux-pumps that may otherwise pump the dye back out of the cells. In this manner, the fluorochrome gains easy access to the intracellular components of the cells.

A further advantage is the fact that the method prevents auto-fluorescence by use of a dye that attaches specifically to nucleic acids and which is excited at light >500 nm (specifically 636 nm). The gain in fluorescence increases $>10x$ upon attachment to the nucleic acids.

The method promotes specific attachment and reduces non-specific attachment by utilising special buffers, and the use of Tris-borate-EDTA, pH 8 has proven to be especially advantageous.

The device according to the invention, which may be used to implement the method, is explained schematically in greater detail in Figure 1.

The device consists of a connection for inlet of urine from a sampling bottle 1. The urine sample is sucked in by pump 2, and the sample is passed on to a mixing chamber or a reagent loop 5. A fixative such as ethanol or acetone is introduced into the mixing chamber 5 by pump 4. The staining solution is kept in receptacle 6 and is led to mixing chamber/reagent loop 8 by pump 7. A common motor 18 can drive pumps 2, 4, 7.

After the mixing has been completed in chamber 8, biological and chemical waste is separated out in a separate receptacle 10. The mixture of the urine sample, the fixative and the staining solution is sent on to the flow cell 11, in which the optical detection takes place. Light scatter is detected using MICROCYTE (Norwegian, European, US patent, pending Japan). For detection in the flow cell, use is made of a carrier liquid from receptacle 12. The amount and velocity of the carrier liquid 12 is adjusted by means of e.g. a throttle valve 9. Following detection of the sample in the flow cell 11, it is sent to waste container 14 by pump 13, which is connected to motor 17. This waste consists mainly of water with a very low content of biological material and chemicals.

The measurement of the urine sample in the flow cell is transferred to a data and control unit, where the results are shown on a display. The results are presented on a display where the fluorescent cells appear separately with a different colour from that of non-fluorescent particles. In addition, the total cell count is shown on the display. Cells in the lower size range from 0.5 to 2 μm are presented as bacteria.

The method and device according to the invention have a number of advantages over prior art, including the fact that they allow quicker and more reliable counting of bacteria in urine.

Using today's conventional plate technique, in which cultivated colonies of bacteria must be determined and counted using the naked eye, the analysis may take from one to several days, and may often require the sample to be sent away for analysis. By using the method and the device of the invention, the results of the analysis are available on site in a matter seconds.

A great advantage of the device is the fact that it is automated. There is no manual handling of chemicals, which removes the risk of the operator being exposed to any chemicals that may be injurious to his or her health.

- 5 The device also ensures a reduced possibility of human errors and failures during the handling and treatment of the sample.

By using the method and the device of the invention, the cost per sample will be lower than that which is the case for the conventional methods of analysis that are in use
10 today.

C l a i m s

1.

A method for counting cells in a urine sample,

c h a r a c t e r i s e d i n t h a t

- a fixative is added to and mixed with the urine sample;
- a buffer solution is added to the mixture, followed by a dye;
- the mixture is analysed in a device that measures light scatter and fluorescence from individual cells; and
- the results are shown directly on a display.

2.

A method according to Claim 1,

c h a r a c t e r i s e d i n t h a t t h e f i x a t i v e i s o f t h e t y p e t h a t r e n d e r s t h e c e l l u l a r m e m b r a n e p e r m e a b l e , a n d m a y b e a c e t o n e , e t h a n o l o r i s o p r o p a n o l , p r e f e r a b l y a c e t o n e .

3.

A method according to Claim 1,

c h a r a c t e r i s e d i n t h a t t h e b u f f e r s o l u t i o n p r o m o t e s a t t a c h m e n t t o t h e n u c l e i c a c i d s o f t h e c e l l s , a n d t h a t i t i s p r e f e r a b l y a T B E - b u f f e r c o n s i s t i n g o f 90 m M T r i s , 90 m M B o r a t , 2 , 5 m M E D T A , p H 8 .

4.

A method according to Claims 1 - 2,

c h a r a c t e r i s e d i n t h a t t h e d y e u s e d i s a f l u o r o c h r o m e t h a t s p e c i f i c a l l y a t t a c h e s t o t h e n u c l e i c a c i d s o f t h e c e l l s , a n d t h a t i t i s a m o n o m e r c y a n i n e f l u o r o c h r o m e , p r e f e r a b l y T O P R O - 3 .

5.

A method according to Claims 1 - 4,

c h a r a c t e r i s e d i n t h a t t h e m i x t u r e i s a n a l y s e d i n a d e v i c e t h a t m e a s u r e s l i g h t s c a t t e r a n d f l u o r e s c e n c e f r o m t h e i n d i v i d u a l c e l l s , s u c h a s a f l o w c y t o m e t e r .

6.

A method according to Claims 1 – 5,
c h a r a c t e r i s e d i n that the analyses are performed at a wave
5 length >500, preferably at 635 nm.

7.

A device for measuring cells in a liquid stream by means of flow cytometry, particularly
bacteria in a urine sample,
10 c h a r a c t e r i s e d i n that it comprises pickup tubes for a urine
sample (1), which tubes lead to one or more mixing chambers (5, 8) to which are also
connected separate receptacles for a fixative (3) and a staining solution (6) that are
added to the mixing chamber (5, 8) via adjustable multi-channel pumps (2, 4, 7, 9), the
mixing chamber further being connected to an optical flow cytometric cell (11) to which
15 is added a carrier liquid from receptacle (12).

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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International Bureau



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PCT

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33/50

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(71) Applicant (for all designated States except US):
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NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
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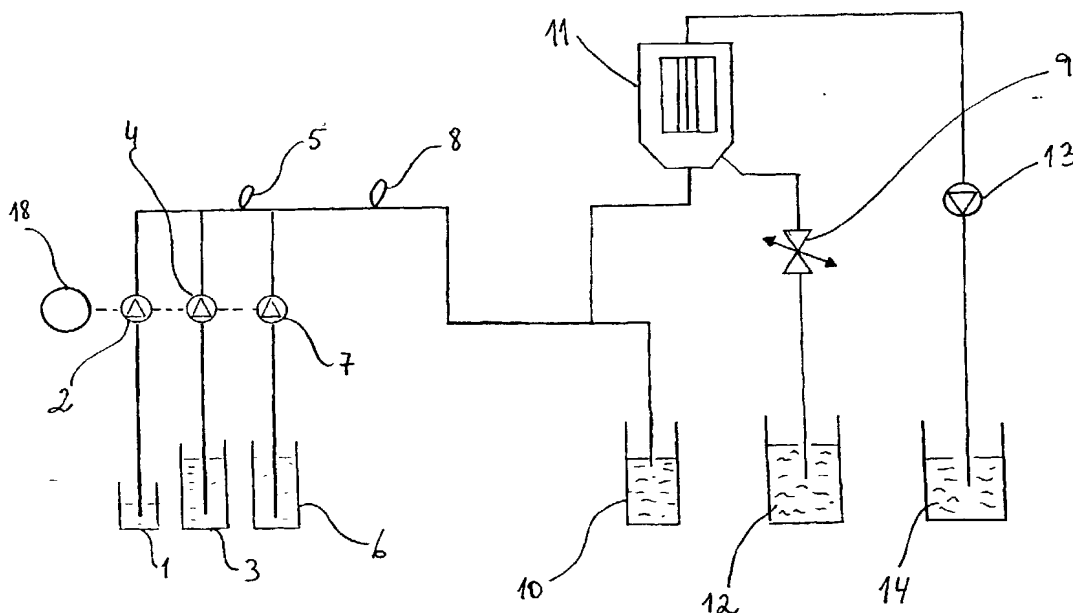
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Published:

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette

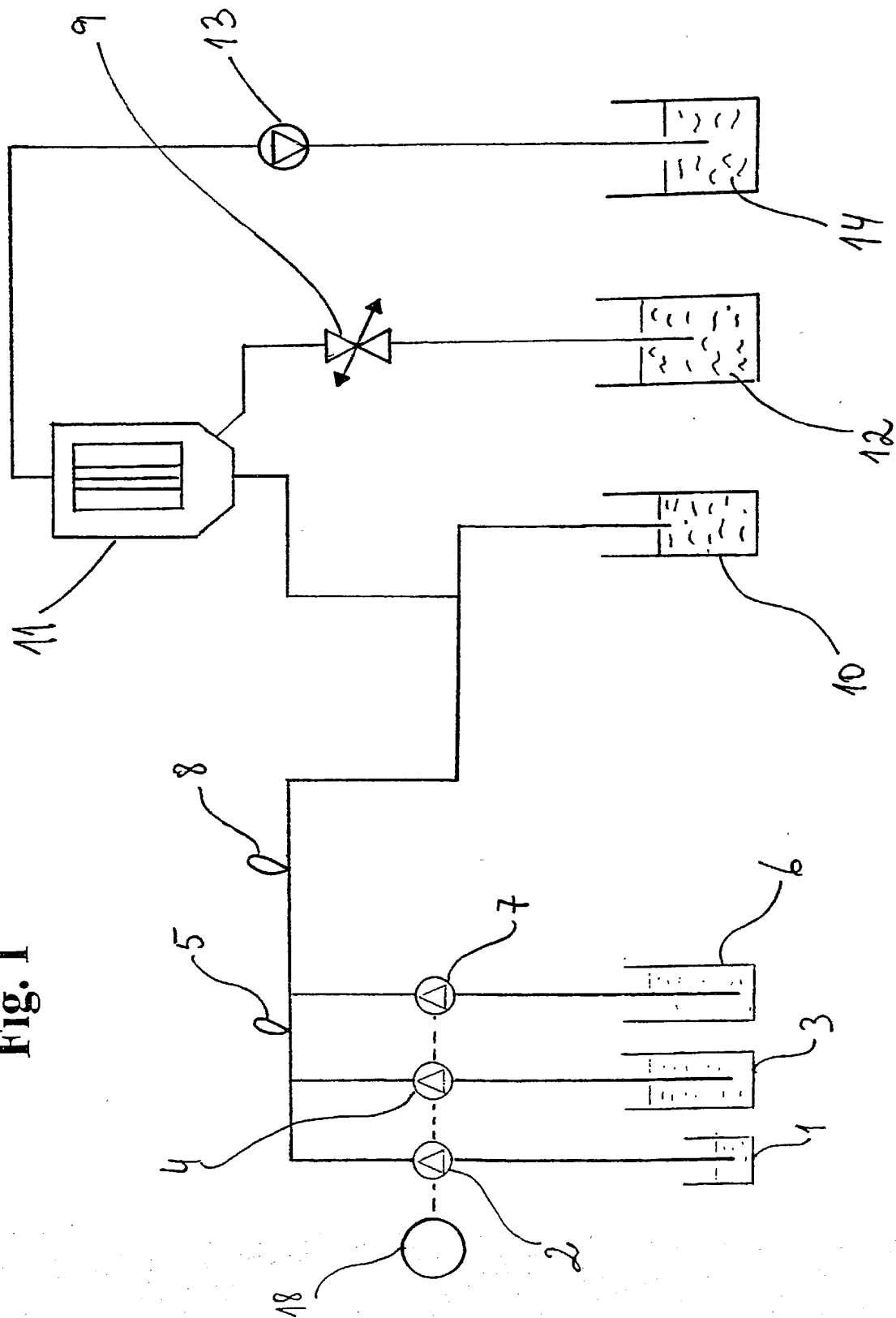
(54) Title: **METHOD AND DEVICE FOR COUNTING CELLS IN URINE**



(57) Abstract: The invention regards a method and a device for measuring the number of cells in urine. A fixative, a buffer and a dye are added to the urine sample, which is then analysed in a device for measuring fluorescence.

WO 01/16595 A1

Fig. 1



<p align="center">DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</p> <p><input type="checkbox"/> Declaration Submitted with Initial Filing <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing</p>		Attorney Docket No.	2800-106
		First Named Inventor	GJELSNES, Oddbjorn
		COMPLETE IF KNOWN	
		Application Number	PCT/NO00/00286
		Filing Date	September 1, 2000
		Group Art Unit	N/A
		Examiner Name	N/A

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: METHOD AND DEVICE FOR COUNTING CELLS IN URINE the specification of which is was filed on September 1, 2000 as PCT International Application Number PCT/NO00/00286 and was amended on February 21, 2002.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Numbers	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
19994228	Norway	09/01/1999	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)

I or we hereby appoint the registered practitioner(s) associated with Customer No. **6449** to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith. Direct all correspondence to Customer Number **6449**.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
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NAME OF SECOND INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
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